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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
10/806,736	03/23/2004	Jerome David	SPINE 3 . 0-423	2555
530 75	90 02/16/2006		EXAMINER	
LERNER, DAVID, LITTENBERG,			SHAFFER, RICHARD R	
KRUMHOLZ &	& MENTLIK			
600 SOUTH AVENUE WEST		ART UNIT	PAPER NUMBER	
WESTFIELD, NJ 07090			3733	
			DATE MAIL ED: 02/16/2006	

Please find below and/or attached an Office communication concerning this application or proceeding.

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	Application No.	Applicant(s)				
Office A 4 4 2 2 2	10/806,736	DAVID, JEROME				
Office Action Summary	Examiner	Art Unit				
	Richard R. Shaffer	3733				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).						
Status						
1)⊠ Responsive to communication(s) filed on 23 M	arch 2004.					
2a) This action is <b>FINAL</b> . 2b) This action is non-final.						
·—	3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is					
closed in accordance with the practice under E						
Disposition of Claims						
4)⊠ Claim(s) 1-33 is/are pending in the application.						
4) Of the above claim(s) is/are withdrawn from consideration.						
5) Claim(s) is/are allowed.						
6)⊠ Claim(s) <u>1-33</u> is/are rejected.						
7) Claim(s) is/are objected to.						
8) Claim(s) are subject to restriction and/o	r election requirement.					
Application Papers						
9)⊠ The specification is objected to by the Examiner.						
10)⊠ The drawing(s) filed on <u>23 March 2004</u> is/are: a)⊠ accepted or b)□ objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).						
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority under 35 U.S.C. § 119						
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).						
a) ☐ All b) ☐ Some * c) ☐ None of:						
1. Certified copies of the priority documents have been received.						
2. Certified copies of the priority documents have been received in Application No						
3. Copies of the certified copies of the priority documents have been received in this National Stage						
application from the International Bureau (PCT Rule 17.2(a)).						
* See the attached detailed Office action for a list of the certified copies not received.						
Attachment(s)						
1) Notice of References Cited (PTO-892)	4) Interview Summary					
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  Paper No(s)/Mail Date  5) Notice of Informal Patent Application (PTO-152)						
Paper No(s)/Mail Date 9/13/2005.	6) Other:	,, , , , , , , , , , , , , , , , , , , ,				
U.S. Patent and Trademark Office PTOL-326 (Rev. 7-05) Office Ad	ction Summary Pa	art of Paper No./Mail Date 20060208				

#### **DETAILED ACTION**

# Specification

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The following title is suggested: Modular Polyaxial Bone Screw and Plate.

# Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 8 recites the limitation "said fingers" in line 2. There is insufficient antecedent basis for this limitation in the claim.

## Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 25, 26, and 30-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Shluzas, et al (US Patent Publication 2002/0143328). Shluzas, et al disclose a bone plate system (**Figure 5**) comprising: a curved (see **Figure 3**) bone plate (212) having a first aperture (250), second aperture (252), and a third aperture (254) extending along a longitudinal axis and having an upper and lower surface; a sliding

element having a top (242) and bottom (270) portion, an aperture extending along a central axis, the top portion having a compression member (lower portion of top 242), the bottom portion having a locking member (upper portion of 270), both the top and bottom portions having inwardly tapered walls (the top is internal, the bottom is external at the base where it interfaces with 240), both portion have a radially outward extending shoulder (286 and 294), and both portions interact with an interior wall of the bone plate aperture (250); a bone fastener (216) having a longitudinal axis, stem which is orientated within the sliding element aperture; a stopping element (240); a threaded locking element (228) having a bore for receiving the stem of the bone screw and includes a concave base (206) and a cap (more easily seen in Figure 3). In Column 5, Paragraph 57, it is further disclosed that the stopping element could have a convex surface with the bottom element having a concave surface to interact. In regard to claims 30-33, Figure 3 clearly demonstrates applicant's method steps.

Claims 1-13, 16-18, and 25-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Lin (US Patent 5,613,968). Lin discloses a system (**Figure 8**) comprising: a bone screw (**300**) having a longitudinal axis, having a stem (**330**) and a bone engaging portion (**31**); a bone plate (**100**) having an aperture (**130**) extending along the longitudinal axis of the bone screw; a sliding element with top (**200**) and bottom (**323**) portion, the top portion having a compression member (**230**) with a plurality of inwardly tapered fingers (**250**, **Figure 3c**) which also have a ridge (bottom of **200**, see **Figure 3c**), the bottom portion having a locking member (edges of **323**) to engage the compression member, an aperture passing through wherein the diameter of the screw

Art Unit: 3733

stem is less than the cross section of the aperture, and both the top and bottom portions having a radially extending outer wall (210 and 323); a stopping element (322); a threaded locking element (400) having a concave base (430) and cap (410).

# Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 2, 5-7, and 9-14, 16-19, and 21-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shluzas, et al. Shluzas, et al disclose all of the claimed limitations except for the stopping element being separable and adjustable by threading. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the stopping element (240) separate from the shaft of the bone screw, since it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art. *Nerwin v. Erlichman*, 168 USPQ 177, 179.

Claims 15 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shluzas, et al. It would have been further obvious to one having ordinary skill in the art at the time the invention was made to construct the removable stopping element (240) with internal threads, since it has been held that the provision of adjustability, where needed, involves only routine skill in the art. *In re Stevens*, 101 USPQ 284 (CCPA 1954).

Application/Control Number: 10/806,736 Page 5

Art Unit: 3733

### Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard R. Shaffer whose telephone number is 571-272-8683. The examiner can normally be reached on Monday-Friday during (7am-5pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Richard Shaffer February 9<sup>th</sup>, 2006

Bichard Shaffer

SUPERVISORY PATENT EXAMINER